



Medical Oxygen Suppliers, Distributors and Manufacturers in Wisconsin

Several questions have been raised concerning the Pharmacy licensure requirements for medical supply companies in Wisconsin, who supply, distribute and/or manufacture medical oxygen. Palmetto GBA, who administers Medicare health insurance for the Centers for Medicare & Medicaid Services (CMS), has advised via their website that such entities must be in compliance with all applicable federal and state licensure and regulatory requirements if such company seeks to receive Medicare reimbursement. Palmetto GBA notes on their website:

A - Effective 03/26/1986 in-state suppliers dispensing oxygen directly to patients must hold a WI pharmacist license and work out of a licensed pharmacy or health care facility (i.e hospital and clinics, nursing facility), unless the oxygen is provided by a licensed practitioner authorized to prescribe and administer drugs in this state. Out-of-state suppliers must hold a Wisconsin out-of-state pharmacy license to provide oxygen to persons in the state of WI.

B - Drug Manufacturing License needed if re-packing/transfilling oxygen tanks, e.g. filling portable tanks from stationary ones.

C - The supplier may dispense prescription items without being licensed as a pharmacy if they are a Remote Dispensing Site and has a licensed supervising pharmacy that oversees the operations and administration of all aspects of the remote dispensing site. Please refer to Wisconsin Administrative Code Chapter Phar 7.095

See <http://www.palmettogba.com/palmetto/providers.nsf/DocsCat/Providers~National%20Supplier%20Clearinghouse~Resources~Licensure%20Information~7GLS4M6340?open&navmenu=||>

The above information appears to have raised questions regarding its accuracy. Accordingly, the following information is provided to assist with any questions.

The FDA identifies oxygen as a legend drug. Prescriptions are required for legend drugs. The definition of “dispense” can be found in Wis. Stat. § 450.01(7). Per this definition, dispense is defined as delivering a prescribed drug or device to an ultimate user pursuant to a prescription order. Wisconsin Stat. § 450.01(16) defines the “practice of pharmacy” to include the dispensing of drugs and devices. Wisconsin Stat. § 450.03(1) provides that no person may engage in the practice of pharmacy unless licensed as a pharmacist. Wisconsin Stat. §§ 450.06(1) and 450.062 require licensed pharmacists to dispense at a location that is licensed as a pharmacy or a remote dispensing site. Accordingly, the dispensing of medical oxygen without proper licensure, is a violation of Wis. Stat. ch. 450 and/or Wis. Stat. § 440.21.

Wisconsin Stat. § 450.07 requires a manufacturing license if an entity in Wisconsin is engaging in manufacturing. Manufacturer and Manufacturing are defined in Wis. Stat. § 450.01(12) and (13). The filling and/or refilling of portable medical oxygen containers would qualify as manufacturing under these sections.

Wisconsin Stat. § 450.071 requires licensure for wholesale distributors of prescription drugs (there is an exemption for manufacturers that distribute prescription drugs manufactured by the manufacturer if licensure is not required under federal law). Wisconsin Stat. § 450.01(8) defines “distribute” as “means to deliver, other than by administering or dispensing.” Accordingly, an entity that distributes medical oxygen to another entity such as a long-term care facility, who will then further distribute or dispense, would require licensure per Wis. Stat. § 450.071. A wholesale distributor’s license does not authorize an entity/facility to dispense prescription drugs directly to patients pursuant to a prescriber’s prescription order. Dispensing directly to patients under a prescription order requires a pharmacist and pharmacy license.

Remote dispensing, per Wis. Stat. § 450.62 allows a pharmacist to dispense at a health care facility, as well as other defined locations, if several requirements are met. Medical supply companies are not listed among the allowable remote dispensing sites. For further information concerning remote dispensing, please see Wis. Stat. § 450.62 and Wis. Admin. Code § Phar 7.095.

April 28, 2014 (DSPA)(Pharmacy Examining Board)



Position Statements Related to Pharmacies Issued by the Pharmacy Examining Board

1. DOES THE PHARMACIST HAVE TO TALK TO A PATIENT ABOUT PRESCRIPTION MEDICATION BEING DISPENSED?

Yes. Consultation is required as per Phar 7.01(1)(e).

Revised: 04/15/2013

2. CAN THE PHARMACY REFUSE TO TAKE BACK PRESCRIPTION MEDICATION?

Yes. A pharmacy is only permitted to take back prescriptions that have been dispensed in limited circumstances, see Phar 7.04(2).

Revised: 04/15/2013

3. CAN THE PHARMACIST GIVE OUT A PATIENT'S PERSONAL HEALTH CARE RECORDS OR INFORMATION?

A pharmacist is a "health care provider" as defined in Wis Stats s146.81(1). As such, a pharmacist is required to comply with state laws regarding confidentiality of patient health care records. For Wisconsin's confidentiality of patient health care record requirements, see Wis stats s.146.82.

Revised: 04/15/2013

4. CAN A PATIENT RECEIVE MORE THAN A 30 DAY SUPPLY OF A CONTROLLED SUBSTANCE?

Yes. Often a patient will need to discuss this issue with their insurance provider who may have limits regarding the amount that can be dispensed at any one time. However, Wisconsin law does not restrict the amount that may be dispensed.

Revised: 05/22/2013

5. WHERE CAN A PHARMACIST FIND INFORMATION CONCERNING THE SALE AND PURCHASE OF PSEUDOEPHEDRINE PRODUCTS?

In 2005, Wisconsin Act 14 took effect, regulating the sale and purchase of pseudoephedrine. The relevant provisions can be found in Wis. Stat. ch. 961, Uniform Controlled Substances Act. In 2006, the United States Congress passed the Combat Methamphetamine Epidemic Act of 2005, which requires any product containing ephedrine or pseudoephedrine, to be strictly regulated to help prevent the production of methamphetamine, an illegal street drug. Pseudoephedrine is a common ingredient in many cold and allergy relief products. The sale and purchase of pseudoephedrine is regulated by federal and state law which is, at times, inconsistent with each other. A pharmacist is required to comply with both laws. Therefore, if federal and state laws are inconsistent, a pharmacist is required to comply with the more stringent provision. Both laws provide for buying restrictions based upon amount, as well as requirements for storage and record keeping. Further information concerning federal law may be found at <http://www.fda.gov/drugs/drugsafety/informationbydrugclass/ucm072423.htm>. Wisconsin Stat. ch. 961 can be found at <https://docs.legis.wisconsin.gov/statutes/statutes/961>.

Revised 12/11/2013

6. CAN A PATIENT RECEIVE ASSISTANCE FROM A PHARMACIST IN REPACKAGING MEDICATIONS TO BETTER ALLOW THE PATIENT OR A CAREGIVER TO MANAGE THEIR MEDICATION ADMINISTRATION? EVEN IF THAT PHARMACIST NEVER DISPENSED THE MEDICATION ORIGINALLY?

Yes. Wis. Stats. ch. 450 and Wis. Admin. Code s. Phar 7.04 permit a pharmacist to assist a patient or an agent of a patient in having a previously dispensed drug or device repackaged, relabeled and subsequently returned to the patient or the patient's agent for the same patient's use, even if the pharmacist did not dispense the drug or device originally. See Wis. Admin. Code s. Phar 7.04(4).

Note, however, there may be other statutory and/or code provisions not governed by the Pharmacy Examining Board that may limit or restrict the practice of repackaging, specifically as it relates to certain patients in long term care facilities and community based residential facilities. For more information, you may wish to refer to applicable rules of the Wisconsin Department of Health Services.

Revised: 09/11/2013

7. DOES WISCONSIN REQUIRE OUT OF STATE PHARMACIES TO BE LICENSED TO DISPENSE IN WISCONSIN?

Yes. A Wisconsin pharmacy license must be obtained by pharmacies licensed in another state which dispense prescription medications, including schedule II controlled substances, by mail or other delivery to patients in this state.

Revised: 05/22/2013

8. HOW MANY DAYS SUPPLY OF A CONTROLLED SUBSTANCE MAY BE DISPENSED AT ONE TIME?

As of August 1, 2002, the PEB revised Wis. Admin. Code § Phar 8.05, the dispensing requirements for controlled substances, removing the 7-day date limitation on schedule II controlled substances prescriptions and eliminating the 34-day dispensing quantity limitation on all controlled substances. The repeal of these sections of Phar 8.05 is intended to allow practitioners and pharmacists to more fully exercise their professional judgment in prescribing and dispensing controlled substances. This is consistent with federal controlled substances prescription rules which have no date or days supply restrictions.

The state requirement that a schedule II controlled substance prescription may not be dispensed more than 60 days after the date of issue still remains.

Revised: 05/22/2013

9. CAN A PHARMACIST DISPENSE A PRESCRIPTION ORDER FOR METHADONE?

Neither Chapter 450 of the Wisconsin Statutes nor Chapter Phar of the Wisconsin Administrative Code specifically prohibits Wisconsin-licensed pharmacists from dispensing a prescription order for methadone. However, there may be applicable federal regulations which contain prohibitions and/or limitations that Wisconsin-licensed pharmacists may be subject to. For applicable federal law, see 21 CFR 1306.04 et seq.
(<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=1306>).

Revised: 09/11/2013

10. CAN A PHARMACIST FILL OR REFILL A PRESCRIPTION ORDER FOR AN OUT-OF-STATE PRESCRIBER?

Yes, Wisconsin pharmacies may legally fill or refill prescription orders from practitioners practicing in another state, if they are licensed in another state and recognized by Wisconsin as a person authorized to prescribe and administer drugs. This includes prescription orders for controlled substances. However, prescription orders for controlled substances are only valid for practitioners having a current federal drug enforcement registration number. A pharmacist should inquire further regarding a practitioner's authority to prescribe if the pharmacist, using professional judgment, is concerned that the prescription order might not be valid.

Revised: 05/22/2013

11. ARE THERE DIFFERENCES BETWEEN FEDERAL SCHEDULING AND WISCONSIN SCHEDULING OF CONTROLLED SUBSTANCES? HOW DO I FIND OUT IF A SUBSTANCE IS CONTROLLED, AND WHAT SCHEDULE IT IS?

The State follows Federal regulations for scheduled drugs, but may also have additional scheduled drugs that are regulated. You will want to consult Chapter 961 of the Wisconsin Statutes and the additions to the schedules through Administrative Rule. Those added in the administrative code can be found in Ch CSB 2. These may be updated periodically, so please check back often.

Revised: 05/22/2013

12. IF AN OUT-OF-STATE MAIL ORDER PHARMACY IS LICENSED IN WISCONSIN, DO THE PHARMACISTS WORKING THERE NEED WISCONSIN CREDENTIALS AS WELL?

No, the pharmacists do not need to be licensed in Wisconsin but they must be licensed in the state where the pharmacy is located.

Revised: 05/16/2013

13. DOES AN OUT-OF-STATE DISTRIBUTOR NEED A LICENSE TO SHIP MEDICATION OR DEVICES TO WISCONSIN FACILITIES?

As of June 1, 2008, distributors of medical devices no longer need a wholesale distributor of prescription drug license to ship medical devices into Wisconsin. Distributors of prescription drugs need to obtain a wholesale distribution license from the Board.

Revised: 07/17/2013

14. DO OUT-OF-STATE DRUG MANUFACTURERS NEED TO BE LICENSED IN WISCONSIN?

Only those manufacturers physically located within Wisconsin need to obtain a drug manufacturer license.

Revised: 07/17/2013

15. CAN A DISTRIBUTOR SHIP PRESCRIPTION MEDICATIONS TO A STORAGE FACILITY AT A DIFFERENT LOCATION THAN THE LICENSED PHARMACY WHERE THEY WILL BE DISPENSED, OR DO THE MEDICATIONS NEED TO BE SHIPPED DIRECTLY TO THE LICENSED PHARMACY?

Wis. Stats. 450.072 regulate the distribution of prescription drugs. Distributors are only allowed to ship prescription medications to a licensed pharmacist. These restrictions apply to delivery of drugs to the premises listed on the pharmacist's license. A distributor may be able to apply for a delivery variance to ship medications to another location.

Revised: 07/17/2013

16. CAN ONE PHARMACY TRANSFER A PRESCRIPTION TO ANOTHER PHARMACY VIA FAX?

Yes, if certain enumerated conditions are met, including verbal verification by both pharmacists. See Ch Phar 7.055 Wisconsin Administrative Code for the specific requirements.

Revised: 09/11/2013

17. CAN A PHARMACIST ADMINISTER VACCINES? CAN VACCINES BE ADMINISTERED TO MINORS?

Under Wis. Stats. 450.035(2), a pharmacist may administer vaccines if they have completed 12 hours of approved education and fulfills the requirements under 450.035(2t). Under no circumstances may a pharmacist or person engaged in the practice of pharmacy administer vaccines to persons under the age of six (6).

Revised: 09/11/2013

18. WHERE DO I FIND ANSWERS TO QUESTIONS RELATED TO EPT (EXPEDITED PARTNER THERAPY)?

- a. What is EPT? Expedited Partner Therapy, or EPT, is a general term for the practice of treating the sex partner(s) of patients diagnosed with Sexually Transmitted Diseases (STDs) without an intervening medical evaluation of the partner(s).
- b. What changes were made in the new law? 2009 Wisconsin Act 280 went into effect on May 26, 2010. The new law: 1) explicitly allows physicians, physician assistants, and certified nurse prescribers to furnish or prescribe medication for EPT and pharmacists to dispense medication for EPT; 2) limits civil liability for medical providers and pharmacists as long as EPT is provided in accordance with the Act; 3) allows the prescription to be written in the partner's name (preferred) or with "Expedited Partner Therapy" or "EPT" in place of a name when the patient does not know or is unwilling to give the partner's name; and 4) requires written materials be developed by the Department of Health Services (DHS) and be distributed to the patient by the medical provider, for use by the partner(s) receiving EPT.
- c. Who is eligible/ineligible for EPT? The Act specifies that EPT can only be used for partners of patients infected with *Chlamydia trachomatis*, *Neisseria gonorrhoeae* or trichomoniasis infections.
- d. Is there a limit to the number of partners that can receive EPT for a given patient? No. EPT allows for the treatment of all of a patient's partners. Treatment of all affected partners will reduce the risk of transmission and re-infection.
- e. Is EPT limited to specific medications? Only Antimicrobial drugs used to treat *Chlamydia trachomatis*, *Neisseria gonorrhoeae* or trichomoniasis can be prescribed using EPT. The Act specifically excludes all controlled substances.
- f. How is EPT delivered to the partner(s)? Medication may be dispensed to the patient by the medical provider to take to his/her partner(s), or separate prescriptions may be written for the patient and his/her partner(s).
- g. Is a pharmacist liable if an adverse event occurs? The Act exempts medical prescribers and pharmacists from civil liability for injury to, or death of, the sexual partner unless an act or omission of the provider involves reckless, wanton, or intentional misconduct.
- h. Who will pay for the partner's medication? The patient's insurance cannot be billed for the partner's medication (unless the partner is covered on the patient's insurance and the
- i. partner information is known). There is currently no state funding to pay for EPT medication. The patient may elect to pay the full cost of the medication for the partner(s).
- j. Are pharmacists required to participate? The Act does not require pharmacists to participate.
- k. Are pharmacists required to give information regarding STDs when consulting a person receiving EPT? The Act requires that the medical provider provide written information to the patient for use by the partner(s) that has information on STDs, their treatment and the risk of drug allergies. The Act also requires that a pharmacist provide consultation in accordance with the rules promulgated by the Pharmacy Examining Board, and also ask whether the partner is allergic to the prescribed medication and advise discontinuing the medication if the person has a known allergy or develops signs of an allergic reaction after taking the medication.

- l. How do pharmacists fill prescriptions for EPT? Pharmacists must meet all of the requirements of the Pharmacy Examining Board for filling prescriptions. Prescriptions must also be labeled according to Wis Stat § 450.11(4) which includes the full name of the patient if known or the words Expedited Partner Therapy or EPT. Consultation is required on each prescription per Phar 7.01(1)(e). The patient may act as the agent of the partner(s) for
- m. purposes of fulfilling the consultation requirement.
- n. How do pharmacists label a prescription without the partner's full name? Pharmacies that choose to dispense EPT prescriptions will likely need to establish a profile for a patient named Expedited Partner Therapy or EPT.

Revised: 10/30/2013

19. Where can I find more information about EPT?

The Wisconsin EPT Act, Frequently Asked Questions documents, provider guidance, and patient information sheets will be available at <http://dhs.wisconsin.gov/communicable/STD/EPT/EPT.htm>

Questions about EPT in Wisconsin can be directed to the Wisconsin Department of Health STD Section at (608) 266-7365.

EPT information and resources from the CDC are available at <http://www.cdc.gov/std/ept>.

Revised: 10/30/2013